

JAN 8 2002

510(k) SUMMARY

K014080

**SUBMITTER:** Dideco S.p.A.  
86, Via Statale 12 Nord  
41037 Mirandola (MO) Italy

**CONTACT PERSON:** Luigi Vecchi  
Phone: 011 39 0535 29811  
Fax: 011 39 0535 25229

**DATE PREPARED:** December 10, 2001

**DEVICE TRADE NAME:** Apex Adult Hollow Fiber Oxygenator

**COMMON NAME:** Hollow Fiber Oxygenator

**CLASSIFICATION NAME:** Cardiopulmonary Bypass Oxygenator.

**PREDICATE DEVICE:** Dideco D 903 Avant Adult Hollow Fiber Oxygenator

**DEVICE DESCRIPTION:**

The Apex Adult Hollow Fiber Oxygenator is a cardiopulmonary bypass blood oxygenator with an integral heat exchanger.

**INDICATION FOR USE:**

The Apex Adult Hollow Fiber Oxygenator is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

**TECHNOLOGICAL CHARACTERISTICS:**

The Apex hollow fiber oxygenator is identical in design to the D 903 Avant adult hollow fiber oxygenator. The only modifications made to the device consist of using a different temperature probe, relocation of the gas connectors, and aesthetic variations that do not change the function of the device. The fundamental scientific technology is unchanged from the predicate device. The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

**NONCLINICAL TEST RESULTS:**

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:1997 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. Tests were performed on devices accelerated aged to an equivalent of five years real time aging. Sterility, pyrogenicity, EO residuals and package integrity testing were also conducted. The results of this testing met established specifications.

**IN VITRO TEST RESULTS:**

*In vitro* testing was carried out in accordance with the requirements of ISO 7199 and the Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff November 13, 2000 to provide the data necessary to demonstrate compliance of the predicate device with safety and effectiveness requirements. The D903 Avant Oxygenator aged to 5 years was tested for gas transfer characteristics, pressure drop, mechanical integrity, hemolysis, cell depletion and device integrity. The results of these tests met established specifications. The modifications

being made to the Apex Oxygenator, do not affect the performance of the device; therefore, the functional and biocompatibility parameters exhibited by D 903 Avant apply to the Apex Oxygenator.

**CONCLUSION:**

The Apex membrane oxygenator is substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 8 2002

Dideco S.p.A.  
c/o Mr. Barry S. Sall, RAC  
Senior Regulatory Consultant  
PAREXEL International West Corporation  
195 West Street  
Waltham, MA 02451-1163

Re: K014080

Trade Name: Apex Adult Hollow Fiber Membrane Oxygenator  
Regulation Number: 21 CFR 870.4350  
Regulation Name: Cardiopulmonary Bypass Oxygenator  
Regulatory Class: Class II (two)  
Product Code: DTZ  
Dated: December 10, 2001  
Received: December 11, 2001

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

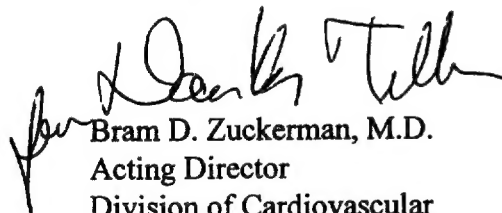
Page 2 - Mr. Barry S. Sall, RAC

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K014080

Device Name: Apex Hollow fiber membrane oxygenator

Indications For Use:

The Apex Hollow fiber membrane oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods up to 6 hours.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K014080

Prescription Use ☒

OR

Over-The-Counter

Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional format 1-2-96)